Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0179861	03/26/2019
Name of Provider or Supplier	**Street Address, City, State**	
Southwest Medical Center	119 Wilson Road, Bentleyville, PA	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of instrument maintenance records, and interview with testing personnel (TP) #1, the laboratory failed to follow the maintenance protocol and document maintenance activities on 1 of 1 Mechanical (serial # 18162094) 1 Channel, 1-10 milliliter Pipette, used to prepare controls for the Cobas Integra 400 plus from 2018 to the date of survey. Finding Include: 1. The Mechanical (serial # 18162094) 1 Channel, 1-10 milliliter Pipette maintenance document states under notes " Check the performance of your pipettor regularly e.g. every 3 months and always after in house service maintenance". 1. On the day of survey, 03/26/2019, TP could not provide maintenance records for 1 of 1 Mechanical (serial # 18162094) one Channel, 1-10 milliliter Pipette, which was last calibrated on 03/06/2018. 2. TP#1 confirmed the finding above on 03/26/2019 around 1:30 pm.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit

	of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of the Cobas Integra 400 plus calibration and quality control records and interview the testing personnel (TP) #1, the laboratory failed to perform calibration verification on the Cobas Integra 400 Plus analyzer at least once every 6 months from 2018 to the day of survey. Finding Include: 1. On the day of survey, 03 /27/2019, the laboratory did not perform calibration verification at least once every 6 months on the Cobas Integra 400 Plus analyzer in 2018 and 2019. 2. The laboratory performed 20,484 patient tests on the Cobas Integra 400 Plus analyzer in 2018. 3. The laboratory performed 1,507 patient tests on the Cobas Integra 400 Plus analyzer in 2019. 4. TP#1 confirmed the findings above on 03/26/2019 around 3:10 pm.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of testing personnel (TP) records and interview the TP#1, the technical consultant (Laboratory director) failed to assess the competency of 1 of 1 TP for moderate complexity testing at least semiannually during the first year the individual analyzed Chemistry and Hematology specimen in 2018. Finding Include: 1. On the day of survey, 03/26/2019, review of personnel records revealed 1 of 1 TP was never assessed for competency before the individual started patient testing in 2018. 2. The laboratory director on 03/26/2019 around 3:30 pm confirmed TP was hired 1/25 /2018 and trained on 03/2018, but their competency was never assessed.